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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

GIBBS, TERRA C

ART UNIT PAPER NUMBER

1635

20

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,658

Applicant(s)

ELLINGTON ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 6,8-11,20 and 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,12-19,21 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13,16,19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This Office Action is a response to the Election filed May 6, 2003, in Paper No. 18.

Claims 1-28 are pending in the instant application.

Claims 6, 8-11, 20, 22-25, and SEQ ID NOs. 1 and 3-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 18.

Claims 1-5, 7, 12-19, 21, and 26-28 have been examined on the merits.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The Declaration does not acknowledge the filing of the provisional application for which the instant application claims benefit.

Nucleotide and/or Amino Acid Sequence Disclosure

The Preliminary Amendment, filed October 22, 2002 in Paper No. 12 is not fully responsive to the previous Notice to Comply with the nucleotide sequence rules found therein, September 21, 2002, because of the following omission(s) or matter(s): Applicant's Sequence

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Listing Amendment is not sufficient to bring the application into compliance with the sequence rules set forth in 37 C.F.R. §1.821-1.825. See Figures 2A, 2B and 3 which contain aptamer constructs but do not have accompanying SEQ ID numbers. These are examples and are not intended to indicate that the Examiner has made an exhaustive review of the application. Applicant must fully comply with the sequence rules for any response to this action to be considered fully responsive.

Election/Restrictions

Applicant's election *without* traverse of SEQ ID NO: 2, in Paper No. 18 is acknowledged.

Information Disclosure Statement

The information disclosure statements filed August 6, 2002, March 7, 2003, and May 19, 2003 in Paper Nos. 13, 16, and 19, respectively are acknowledged. However, references B7 and B10 of the information disclosure statement filed in Paper No. 16 and references B14, C11 and C14 of the information disclosure statement filed in Paper No. 19 have not been considered on the merits because English translations have not been provided. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, 12-19, 21, and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5, 7, 12-19, 21, and 26-28 read on an aptazyme construct comprising a regulatable domain Group I intron aptamer oligonucleotide sequence having a regulatory domain.

The scope of the claimed invention encompasses an aptazyme construct comprising a regulatable domain Group I intron aptamer oligonucleotide sequence having a regulatory domain. The specification as filed provides only a description of a Group I theophylline dependent intron aptamer construct (see Figure 1).

The specification provides only a description of a Group I theophylline dependent intron aptamer construct. However, the specification as filed, does not provide sufficient description that would allow one of skill in the art to use this information to predict the structure of an aptazyme construct comprising a regulatable domain Group I intron aptamer oligonucleotide sequence having a regulatory domain. Additionally, the specification as filed does not define

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“aptazyme” or “Group I intron aptamer” in such clear and concise terms to allow one skilled in the art to know how to identify the physical structure or characteristics of these terms (see 35 U.S.C., 112 second paragraph rejection below against claims 1-5, 7, 12-19, 21, and 26-28 for indefiniteness).

See the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, “Written Description” Requirement (Vol. 66, No. 4, pages 1099-1111). These guidelines state that: “To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.”

Additionally, “[T]he skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims

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directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Applicant's specification does not provide a sufficient number of representative species of an aptazyme construct comprising a regulatable domain Group I intron aptamer oligonucleotide sequence having a regulatory domain, which would allow one of skill in the art to predict the structures of all members of the claimed genus of compounds. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Therefore, the specification does not describe the claimed compounds in such full and concise terms so as to indicate that the applicant had possession of these compounds at the time of filing of this application. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7, 12-19, 21, and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 7, 12-19, 21, and 26-28 recite the terms "aptazyme" and "Group I intron aptamer". It is unclear what is meant by "aptazyme" and "Group I intron aptamer" as these are not art recognized terms. It is noted that an "aptamer" is defined in the instant Specification on page 13, lines 3 and 4 as an oligonucleotide having aptazyme activity. It is further noted that the

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term "regulatable aptazyme" is defined in the Specification at page 12, lines 11 and 12 as an allosteric ribozyme. However these definitions are circular and unclear. How does the skilled artisan identify an aptazyme or a Group I intron aptamer as to their physical structure or characteristics? Without a specific definition in the application as filed as to what these terms are, one of ordinary skill in the art is not apprised of the metes and bounds of the claim. Clarification is required.

Conclusion

No claims are allowable. In view of the 112 first paragraph rejection for written description and the 112 second paragraph rejection for indefiniteness, the terms presented in the claims are not art-recognized terms and therefore it cannot be determined at this time whether prior art exists regarding the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg

July 24, 2003



KAREN LACOURCIERE
PATENT EXAMINER